

**Appendix 1(originally submitted with 09/416,017)
In the United States Patent and Trademark Office**

Applicant: Joar Opheim
Serial Number: 09/416017
Filed: Oct. 6, 1999
Examiner: Isis Ghali
Group Art Unit: 1615

DECLARATION UNDER 37 C.F.R. Section 1.132

I, Joar Opheim declare and say as follows:

That I am a citizen of Norway and reside at 226 Kingsbury Drive, Aptos CA 95003.

That I am the inventor and applicant in the above identified patent application.

That I graduated from Bodo College in Bodo, Norway with a Intermediary degree in Mathematics in 1982, and that I graduated from M.I. University in Oslo Norway with an Intermediary degree in Science in 1984, and that I graduated from University of Oregon in Eugene, OR with a Bachelor degree in Science in 1986.

That I have applied my chemistry background over the last eleven (11) years to the study of fish oil processing improvements with the goals of improving quality (in particular freshness, purity, and concentration levels) and human consumption of Omega-3 fatty acids from fish. I founded Nordic Naturals in 1994, and am the managing partner. Nordic Naturals produces and sells fish oil based nutritional supplements which include Omega-3 fatty acids, including DHA and EPA and particularly fish oil products in flavored soft gelatin capsules.

That I am familiar with the above identified application and with the references cited by the examiner.

That I learned from experimentation in developing a palatable Omega-3 fatty acid fish oil supplement in a gelatin capsule that a palatable formulation requires both a pleasant tasting gelatin capsule, and a gelatin capsule composition which protects the fish oil from exposure to air. I also found that the addition of flavoring to the fish oil capsule filling improves the palatability further. I found that protecting the fish oil from contact with air is important for fish oil capsules because the fresh fish oil does not have the characteristic "fishy" odor and taste which results in the unpalatable character generally associated with fish oil. I found that once the "fishy" taste develops it can not be effectively covered up by flavoring and will be unpalatable to many people.

That I tested a number of natural flavorings for the gelatin capsules and found that suitable flavoring occurred within a surprisingly narrow range of concentrations, between about 0.25% and 1.50% flavoring. I began by having a series of capsules made for me

while varying the concentration and type of flavorings. I tested at least ten different natural flavors including strawberry, lemon, peppermint, peach, orange and plum. When these tests were started there was no guidance from the manufacturer of the capsules, because while they were a manufacturer of gelatin capsules, there had been no prior experience in making flavored soft gelatin capsules. I started using what turned out to be too high of concentrations of flavors between 5 and 10 % by weight of a flavor and found that these flavor concentrations were not palatable and indeed not consumable. After many tests I found that acceptable tasting gel capsules could be made between about 0.5 % and 1.5% from a wide range of natural flavorings. One of the final test panels for a series of capsules made with water soluble strawberry flavor (Firmenich 52311A) is given in Table 1, below (a copy of the original test memorandum dated 5/14/99 is attached hereto).

Table 1

Test Results for Flavored Gel Capsules (water soluble Firmenich Strawberry #52311, lot 11050265 flavor)

| Per Cent Flavoring (% of shell) | Observation |
|---------------------------------|---------------------------------|
| 0.25% | Distorted Flavor |
| 0.50% | Flat flavor-off flavor |
| 0.75% | Good natural taste |
| 1.00% | Somewhat distorted, harsh taste |
| 1.25% | Harsh taste, after-taste |
| 1.50% | Harsh taste - very soft capsule |

Note that there was surprisingly an optimum taste between about 0.5% and 1.0% flavor, that below 0.5% was not a pleasant taste, and that as the flavor was increased above 1% to 1.5% the flavor became undesirable and the capsule also became unacceptably soft (see discussion of softness below).

That I found from long term testing that the most palatable flavoring for the capsule was different after a period of aging than for a fresh capsule depending on the nature of the oil used to fill the capsule (example EPA/DHA ratio and the total Omega -3 content) so that the most palatable flavor content of the gelatin capsules actually varied among 0.5%, 0.75% and 1% depending on the nature capsule filling.

That I also learned from making and storing capsules of oil over periods over eight months, that the hardness of the capsule was critical to making a capsule which would protect the fish oil from exposure to air (oxygen). Fresh fish oil takes on the characteristic "fishy" taste and odor when exposed to air. Once this characteristic is present, even flavored capsules and oil are not palatable to many people. Allowing for the production, sales and distribution cycle, it is necessary for fish oil capsules to be stable for at least one to two years, so preventing this deterioration is critical to making a palatable fish oil supplement.

That I found that capsules having from about 6 to 10% water and from 0.25 to about 1.25% flavor had a particular hardness which does not allow the oil to deteriorate even

over periods of time greater than eight months. The oil in softer capsules (the difference in hardness was readily noticeable by physical inspection), typically containing over 12% water content, took on an unacceptable odor in less than eight months. Harder capsules (less than about 3% water content) often developed small cracks which exposed the oil to air and developed an unacceptable odor. I also found that these harder capsules were also unpleasant to the taste because the flavor was not evenly distributed in the capsule.

For the above tests a typical capsule composition was 62% gelatin, 29% glycerol, 8% water and 1% natural flavoring. The water and flavoring content, of course, was varied keeping the ratio of other ingredients approximately constant.

That I also found the most palatable capsules when the filling and capsule contained about the same flavor concentration.

That I do not believe that it was known how to make a palatable fish oil supplement in a flavored gelatin capsule prior to my research and development, nor that the development would have been at all obvious to those skilled in the art.

That I directed Banner Pharmacaps Europe B.V. (Netherlands) in doing the research as described above, which led to the palatable fish oil capsules. Banner Pharmacaps is the second largest producer of soft gelatin capsules in the world and they were unable to lead me to a palatable formulation without the above described extended experimental program which lasted over eight months. They had no prior experience in producing a flavored gel cap palatable fish oil product.

In particular I do not believe that the prior art provides a basis to anticipate the following without having learned it by extensive experimentation:

1. That there would be an optimum flavor content, beyond which palatable fish oil capsules could not be made.
2. That the flavor content for a palatable capsule was between 0.25% and 1.25% for a wide variety of natural flavors.
3. That the flavor content would affect the capsule hardness.
4. That the water content of the capsules, would be a critical factor for producing a fish oil supplement capsule which retains palatability.
5. That the best range of water content for long term oil palatability is 6 to 10% water.
6. That water content above 12% or below 3% are inconsistent with long term palatability of fish oil capsules.

11/30/2005 19:44 8317244658

NORDIC NATURALS

PAGE 02

To: Joar Opheim Page 5 of 5

2005-12-08 22:02:48 (GMT)

15103720590 From: Howard Lebowitz

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing hereon.

Date 12/07/05Joar Opheim